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4 UNITED STATES DISTRICT COURT
5 WESTERN DISTRICT OF WASHINGTON
6 AT SEATTLE

7 IN RE: PHENYLPROPANOLAMINE (PPA)
8 PRODUCTS LIABILITY
9 LITIGATION,

MDL NO. 1407

10 This document relates to all actions

ORDER GRANTING PLAINTIFFS'
MOTION TO REMOVE
CONFIDENTIALITY
DESIGNATIONS OF WYETH
PURSUANT TO CMO 2

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13 I. INTRODUCTION

14 The plaintiffs in Multidistrict Litigation 1407 have moved, under seal, to lift the
15 confidentiality designations on certain documents produced by defendant Wyeth. Plaintiffs further
16 move to unseal the motion and all related supporting documents. Having reviewed the pleadings
17 filed in support of, and opposition to, this motion, and, being fully advised, the court finds and
18 rules as follows:

19 II. BACKGROUND

20 Case Management Order No. 2 ("CMO 2") limits the disclosure of discovered
21 confidential documents in appropriate circumstances. Specifically, CMO 2 permits the
22 confidentiality designations of discovery material "containing trade secrets, or other confidential
23 or proprietary research, development, manufacturing or commercial or business information"
24 CMO 2, ¶ 3. It also allows a party, following good faith negotiation attempts, to dispute a
25 confidentiality designation by motion to the court "at any time.... for any reason." Id. ¶ 10.a. In
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1 the event such a challenge is brought, CMO 2 places the burden of proof for establishing the
2 propriety of confidentiality designation on the designating party. Id.

3 In an October 2, 2002 order in a previous dispute in the MDL, the court ruled
4 on the propriety of a number of confidentiality designations by defendant Novartis Consumer
5 Health. The court held that the confidential designations were proper only for certain discrete
6 information and lifted the remaining designations. Specifically, the court held that Novartis
7 could only designate documents containing: (1) current and confidential product formulas and
8 technological information; (2) cost of product conversion figures that would reveal current and
9 confidential cost and profit margin information; or (3) information relating to a line of products
10 currently under consideration for development or constituting a realistic potential line of future
11 products. The court ordered the parties to apply all future confidentiality designations in
12 accordance with the October 2, 2002 order.

13 Pursuant to CMO 2, Wyeth designated as confidential many of the documents it produced
14 during discovery. Plaintiffs disputed the designations, claiming that they were not appropriate
15 under the terms of CMO 2 or the October 2, 2002 order. Through the meet-and-confer
16 process, Wyeth agreed to withdraw the designations on all but a small group of documents.
17 Plaintiffs then moved to lift the designation on five of the remaining documents, as well a
18 designation on a section of deposition testimony. In its opposition to the motion, Wyeth further
19 agreed to withdraw the designation on one of the challenged documents as well as the deposition
20 designation. As such, the parties' dispute now centers on two documents: (1) a December 20,
21 1993 memorandum regarding the efficacy and safety of certain Dimetapp and Robitussin
22 products (the "December 1993 Memorandum"); and (2) an October 28, 1999 document entitled
23 "Dimetapp PPA Reformulation" (the "Dimetapp Reformulation Document").¹

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25 ¹Originally, plaintiffs also challenged a document that Wyeth claimed contained financial
26 information owned by a third party, AC Nielsen. AC Nielsen filed a brief opposing plaintiffs'
motion to remove the confidentiality designation on that particular document, but later withdrew

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3 III. DISCUSSION

4 A. Standard

5 As the Ninth Circuit has stated, “[g]enerally, the public can gain access to litigation
6 documents and information produced during discovery unless the party opposing disclosure
7 shows ‘good cause’ why a protective order is necessary.” Phillips v. GMC, 307 F.3d 1206, 1210
8 (9th Cir. 2002). CMO 2 allows the MDL parties to designate discovered documents confidential,
9 but maintains this good cause standard in the face of challenges to those designations. CMO 2, ¶
10 10.a.3. Wyeth, as the party seeking protection, bears the burden of showing good cause as to why
11 the documents are entitled to confidentiality designations. Id. ¶ 10.a; accord Fed. R. Civ. P.
12 26(c). “For good cause to exist, the party seeking protection bears the burden of showing specific
13 prejudice or harm” Phillips, 307 F.3d at 1210; San Jose Mercury News, Inc. v. United States
14 Dist. Ct., 187 F.3d 1096, 1102 (9th Cir. 1999) (holding that to gain a protective order the party
15 must make “particularized showing of good cause with respect to any individual document”).
16 ““Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning, do not
17 satisfy the Rule 26(c) test.”” Beckman Indus. v. International Inc., 966 F.2d 470, at 476 (9th Cir.
18 1992) (quoting Cipollone v. Liggett Group, Inc., 785 F.2d 1108, 1121 (3d Cir. 1986).

19 B. Analysis

20 The Court must determine whether good cause exists to prevent the disclosure of the
21 documents at issue. Phillips, 307 F.3d at 1210. As such, the court will examine the documents
22 themselves and the arguments proffered by Wyeth in support of the confidentiality designations.

23
24 1. The December 1993 Memorandum

25
26 its opposition.

1 The December 1993 Memorandum is an internal Wyeth memorandum which analyzes
2 various clinical studies of certain Wyeth products when they contained phenylpropanolamine
3 (“PPA”), and contains a recommendation on pediatric dosing. Originally Wyeth designated the
4 entire document confidential pursuant to CMO 2 ¶ 3(c), which identifies clinical studies as a
5 category of documents subject to a confidential designation by the parties. However, Wyeth later
6 agreed to withdraw its confidentiality designation on all but the “Adverse Event (Safety)” and
7 “Efficacy” data included on a chart in the memorandum.

8 Wyeth argues that the designation is proper because the data constitutes a trade secret.
9 Specifically, Wyeth claims that the efficacy data is both confidential and commercially valuable to
10 the company because it can be applied to Wyeth’s current pseudoephedrine (“PSE”)-containing
11 products.² Wyeth also claims that if either the safety or efficacy data is made public, its
12 competitors could use it in their marketing and/or advertising strategies.

13 Plaintiffs dispute Wyeth’s ability to show good cause for the confidentiality designation.
14 They argue that the clinical study data is stale—it is more than a decade old—and pertains to a drug
15 that is no longer on the market. They contend that Wyeth’s argument that some of the efficacy
16 data can be applied to Wyeth’s current PSE-containing products is overly vague and fails to
17 satisfy the company’s burden to articulate specific harm that will result absent a protective order.
18 Plaintiffs also rely on the October 2, 2002 order in which the court rejected Novartis’ designation
19 of documents that compared the safety of PPA to PSE. The court found it “highly unlikely that
20 [Novartis’] review of studies and literature pertaining to one of its drugs and a potential
21 replacement product constitutes an innovative practice within the pharmaceutical industry.”
22 October 2, 2002 Order at 6-7. Plaintiffs contend that the same reasoning should apply to this
23 dispute because there is nothing secret about a general description of studies and Wyeth’s
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25 ²Wyeth claims that the efficacy of PPA is analogous in certain respects to the efficacy of
26 PSE.

1 impression of them.

2 Once a common law concept, trade secret protection is now governed by statutes in most
3 states. The Uniform Trade Secret Act defines a trade secret as:

4 information, including a formula, pattern, compilation, program, device, method,
5 technique, or process that: (i) derives independent economic value, actual or
6 potential, from not being generally known to, and not being readily ascertainable
by proper means by, other persons who can obtain economic value from its
disclosure or use; and (ii) is the subject of efforts that are reasonable under the
circumstances to maintain its secrecy.

7 Unif. Trade Secrets Act § 1(4) (1985). The principal considerations in determining whether a
8 trade secret exists is whether the information is confidential and whether it is commercially
9 valuable to the holder. Encyclopedia Brown Prods. v. Home Box Office, 26 F. Supp. 2d 606, 613
10 (S.D.N.Y. 1998).

11 The court is not convinced that the efficacy and safety data remains commercially valuable
12 to Wyeth. The data is over a decade old and pertains to the efficacy and safety of products that
13 have not been on the market for at least three years. As such, the court is not persuaded that
14 disclosure of the data to Wyeth's competitors would cause Wyeth competitive harm.³ See In re
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17 ³Wyeth argues that the age of the data does not necessarily make it stale. For support,
18 Wyeth cites Joint Stock Soc'y v. UDV North America, Inc., 104 F. Supp. 2d 390, 409 (D. Del.
19 2000) in which the court upheld the protection of old vodka formulas despite the fact that they
20 were no longer marketed, and Culinary Foods, Inc. v. Raychem Corp., 151 F.R.D. 297, 303
21 (N.D. Ill. 1993), in which the court upheld the protection of pre-1987 marketing plans even
22 though the defendant stopped manufacturing the product in 1986. However, the potential harm
23 to those parties seeking protection was far greater than what Wyeth faces. In Culinary Foods, the
24 court granted protection because the information sought could have revealed substantial
25 information about the movant's current development, business strategy and product development
26 plans. Culinary Foods, 151 F.R.D. at 297. In Joint Stock, the plaintiffs sought information which
contained the precise formulas for the defendants' flavored vodka. Joint Stock, 104 F. Supp. 2d
at 409. The court held that the defendants were entitled to protection because the information
sought by the plaintiffs could confer a "windfall upon defendants' competitors, which included
plaintiffs, because these companies 'could use the information to begin making their own flavored
vodkas'...in addition...the public disclosure of this information would deprive the defendants of
the 'opportunity to license these formulas to a company that was interested in producing flavored
vodka.'" Id.

1 “Agent Orange” Prod. Liab. Litig., 104 F.R.D. 559, 575 (E.D.N.Y. 1985) (stating that an
2 important factor in determining whether disclosure will cause competitive harm is whether the
3 information that the party seeks to protect is current or stale).

4 The court finds that Wyeth’s contention that the efficacy data remains relevant to its
5 current product formulations because the efficacy of PPA is “analogous in certain respects” to
6 that of PSE is not sufficient to warrant a designation. As the court previously stated in its
7 October 2, 2002 order, if the December 1993 Memorandum contained precise formula or other
8 technological information, such information may be properly redacted. However, the reasons that
9 compel confidentiality for actual product formulas do not exist with regard to data concerning the
10 effectiveness or adverse effects of a product, particularly a product that is no longer marketed.

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12 In addition, Wyeth has failed to demonstrate that it would suffer serious harm if the data
13 was disclosed to its competitors. Wyeth’s vague assertion that its competitors could use this data
14 in their marketing and/or advertising strategies seems highly unlikely given that the data relates to
15 a product no longer on the market and is simply too speculative to warrant a confidentiality
16 designation. As such, the court finds good cause lacking for Wyeth’s confidential designation on
17 the efficacy and safety data in the December 1993 Memorandum.

18 2. The Dimetapp Reformulation Document

19 The Dimetapp Reformulation Document is part of a larger document entitled “PPA
20 Reformulation/Commercialization Options” dated October 28, 1999. Wyeth originally designated
21 the entire document confidential as proprietary marketing information pursuant to CMO 2 ¶ 3(b).
22 Wyeth later agreed to withdraw the designation on all but a portion of the document pertaining to
23 Attitude and Usage (“A&U”) data. Wyeth claims that the A&U data was gathered and
24 customized at its request, for which it paid between \$200,000 to \$500,000, and on which it bases
25 its current marketing strategies. Wyeth alleges that the disclosure of this information to Wyeth’s
26 competitors would reveal internal marketing strategy information that is unique to Wyeth and

1 could result in competitive harm to its business. Wyeth argues that the confidential designation
2 on the A&U data is appropriate in light of the October 2, 2002 order in which the court stated
3 that proprietary information relating to a current line of products or future products could be
4 redacted as confidential.

5 Plaintiffs argue that Wyeth does not state a legitimate reason for keeping the data
6 confidential, but rather, resists disclosure of the data simply because it shows that the company
7 was concerned that reformulating its product could lead to the loss of half of its sales. The
8 Plaintiffs also point to the fact that in the October 2, 2002 order, the court lifted Novartis'
9 designation of documents that showed that the company monitored the status of its reformulation
10 efforts, conducted research, and made decisions based on issues such as the cost of conversion,
11 sales, and market research holding that "except to the extent that the reformulation documents
12 may contain current formulas and technological information properly redacted as confidential, the
13 court does not find good cause to exist for these confidential designations." October 2, 2002
14 Order at 11.

15 The court finds that Wyeth has failed to show good cause as to why the A&U data is
16 entitled to a confidential designation. The court addressed a similar issue in the Novartis dispute.
17 There, Novartis sought to designate a number of exhibits that related to the company's
18 reformulation efforts for its products containing PPA. The court agreed that good cause existed
19 to maintain the confidentiality on the portions of any exhibits that contained precise formulations
20 that remained current and confidential. However the court lifted the designation on those
21 portions of the documents that related to the factors considered and the reformulation efforts
22 undertaken by Novartis. The court held that the fact Novartis monitored its reformulation efforts,
23 researched and acted against adverse campaigns, and considered cost of conversion, sales, and
24 market research, is unlikely to come as a surprise to any of its competitors. The court also noted
25 that the documents were outdated and related to products that had already been converted.
26 Similar to Novartis' market research on its reformulation process, the fact that Wyeth considered

1 the product's taste and its corresponding effect on potential sales is unlikely to come as a surprise
2 to any of Wyeth's competitors. This coupled with the fact that the data is at least five years old
3 and relates to a product no longer on the market also works against the asserted need for
4 confidentiality.

5 Wyeth's reliance on the court's statement in the October 2, 2002 order that documents
6 containing information relating to a line of products currently under consideration for
7 development may be confidential is misplaced. In the earlier dispute, Novartis wanted to protect a
8 document that contained consumer research on the viability of a product line targeting a certain
9 group of consumers. In that circumstance, the court held that it would be proper to designate
10 confidential documents that would reveal information relating to products currently under
11 development, or a realistic line of future products. In the present case, the A&U data does not
12 relate to a current or future product, it relates to the reformulation of a product that already took
13 place. Accordingly, the court concludes that Wyeth lacks good cause to maintain a confidentiality
14 designation for the A&U data in the Dimetapp Reformulation Document.

15 IV. CONCLUSION

16 For the foregoing reasons, the court hereby GRANTS plaintiffs' motion to remove the
17 confidentiality designations on the efficacy and safety data in the December 1993 Memorandum
18 and on the A & U data in the Dimetapp Reformulation Document pursuant to CMO 2. The court
19 further GRANTS plaintiffs' request to unseal this motion and the corresponding briefing.

20 DATED at Seattle, Washington this 13th day of July, 2004.

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22 s/ Barbara Jacobs Rothstein
23 BARBARA JACOBS ROTHSTEIN
24 UNITED STATES DISTRICT JUDGE
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